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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,574	12/03/2003	Gudmundur Fertram Sigurjonsson	SIGU3011/JJC	5131

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ALEXANDRIA, VA 22314

EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/725,574

Applicant(s)

SIGURJONSSON ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12, 14-20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 14-20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/31/07.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments with respect to claims 12 and 14-23 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As a result of the amendment to claim 12, claims 12 and 17 are now directed to different embodiments of the claimed invention, thus making dependent claim 17 inconsistent with claim 12 and directed to a combination of embodiments for which there is no support in the disclosure. Claim 18 is rejected because it depends from claim 17.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12, 14-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abuelyaman et al (U.S. Patent No. 7,005,143).

With respect to **claim 12**: Abuelyaman teaches a wound dressing 10 having opposed outermost backside and bodyside surfaces, the bodyside surface being generally planar and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent a wound surface, the dressing comprising: an absorbent core 12 defining opposed proximal and distal surfaces, the distal surface including a central portion and a border portion; a liquid impervious, vapor permeable backing layer 18 defining opposed proximal and distal surfaces, the proximal surface of the backing layer 18 extending over the distal surface of the absorbent core 12 as is seen in Fig. 1, and defining a border portion extending beyond and surrounding peripheral edges of the absorbent core 12, the distal surface of the backing layer defining the backside surface of the wound dressing 10; a first skin adherent facing layer 20 secured only to the proximal surface of the border portion of the backing layer and surrounding the peripheral edges of the absorbent core 12 inasmuch as Abuelyaman teaches that the backing layer 18 and the first facing layer 20 with adhesive film 26 are constructed to form a pocket, pouch or envelope that surrounds the gel layer, i.e. layer 12, a proximal surface of the first facing layer 20 defining a portion of the bodyside surface of the wound dressing and a second facing layer in the form of a second absorbent layer directly secured to and considered herein to be coextensive with the proximal surface of the absorbent core 12, as Abuelyaman teaches that the two absorbent sublayers together form one absorbent structure.

Abuelyaman does not explicitly teach a proximal surface of the second facing layer that defines a portion of the bodyside surface of the wound dressing 10. However, since

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Abuelyaman teaches that the facing layer may comprise an adhesive layer and it is known in the art to surround an absorbent core of a wound dressing with adhesive, it would be obvious to one of ordinary skill in the art to modify the facing layer 20 taught by Abuelyaman with adhesive layer 26 present thereon, which is only adhered to the backing layer at the periphery of the core 12 to form a pocket, such that the facing layer only surrounds the periphery of the core instead of extending over the proximal surface of said second absorbent layer and contains a coextensive adhesive layer 26 secured thereto with a reasonable expectation of success. Thus a proximal surface of the second facing layer would define a portion of the bodyside surface of dressing 10 and be generally co-planar with the proximal surface of the first facing layer 20, because if the first facing layer with adhesive layer 26 thereon is modified such that it only extends around the periphery of the core defining the second facing layer, the second facing layer would necessarily be generally co-planar with the proximal surface of the first facing layer 20 and the periphery of the second facing layer is necessarily contiguous with a periphery of the first facing layer, because they share a boundary defined by the peripheral edge of gel layer 12. The bodyside surface of the wound dressing would thus consist of the proximal surfaces of the first and second facing layers.

Abuelyaman teaches that the second facing layer (i.e. the second absorbent layer) has adhesive properties. The term "adhesive properties" is considered herein to include skin adherent properties. Abuelyaman does not explicitly teach that the second facing layer is composed of a skin adherent hydrophobic silicone gel. However Abuelyaman teaches that the second absorbent layer/second facing layer functions as a barrier between the first absorbent layer comprised of the instant gel material and is less absorbent than said gel material. Since Abuelyaman teaches that the gel material comprises a hydrophobic monomer, it would be obvious to one of ordinary skill in the art to modify the second absorbent layer/second facing

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layer so as to be comprised of a skin adherent hydrophobic gel. Silicone gel is an example of a hydrophobic gel that would accomplish the identical function of acting as a barrier to other hydrophobic gel monomers taught by Abuelyaman, therefore it would be obvious to one of ordinary skill in the art to modify the article of Abuelyaman such that the second facing layer comprises a skin adherent hydrophobic gel with a reasonable expectation of success to preserve the function of the second facing layer as a barrier between the wound and said first absorbent layer.

Abuelyaman does not teach that the second facing layer is perforated. However since Abuelyaman teaches that the first facing layer 20 is perforated and teaches that the perforations 24 conduct exudates from the wound, it would be obvious to one of ordinary skill in the art to modify the second facing layer such that said second facing layer is perforated as taught by Abuelyaman for the first facing layer, since both facing layers are coplanar and their proximal surfaces define a continuous bodyside surface contacting the wound.

With respect to **claim 14**: The border portion of the backing layer 18 is substantially parallel with the distal surface 16 of the absorbent core 12. (Fig. 1)

With respect to **claim 15**: The border portion of the backing layer 18 includes at least two opposed elongate sections, each opposed elongate section extending from a corresponding side of the absorbent core 12. (Col. 19, lines 57-60)

With respect to **claim 16**: Abuelyaman teaches by reference to RE 24,906 to Ulrich that the first facing layer 26 is a pressure sensitive adhesive. (Col. 18, lines 51-57, '906, Col. 1, lines 18-20)

With respect to **claim 17**: The first facing layer 26 extends along the entire proximal surface of the backing layer 18. (Fig. 1)

With respect to **claim 18**: The first facing layer 26 is sufficiently porous so as not to occlude moisture transmission through the backing layer 18. (Col. 19, lines 20-28)

With respect to **claim 19**: The first facing layer 26 has greater skin adherence properties than the second facing layer 20, as Abuelyaman teaches that the adhesive of layer 26 is a pressure-sensitive adhesive typically used to adhere substrates to skin, while the adhesive present on layer 20 is an adhesive other than a pressure-sensitive adhesive. (Col. 18, lines 36-57)

With respect to **claim 22**: Abuelyaman teaches a wound dressing 10 having opposed bodyside and backside surfaces, comprising: an absorbent core 12 defining opposed proximal and distal surfaces 14,16, respectively, the bodyside surface being generally planar as can be seen in Fig. 1 and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent a wound surface; a liquid impervious, vapor permeable backing layer 18 defining opposed proximal and distal surfaces, the proximal surface of the backing layer 18 extending over the distal surface 16 of the absorbent core, and defining a border portion 22 extending beyond and surrounding peripheral edges of the absorbent core 12, the distal surface of the backing layer defining the backside surface of the wound dressing 10; and a continuous skin adherent facing layer 26 composed of a skin adherent hydrophobic gel and directly secured to both the proximal surface 14 of the absorbent core and the border portion 22 of the backing

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layer, the facing layer 26 defining a pattern of through extending apertures only along the portion thereof bounded by the peripheral edges of the absorbent core 12, the facing layer 26 defining the bodyside surface of the wound dressing 10. (Fig. 1, Col. 19, lines 16-28, 53-67, Col. 20, lines 1-9)

Abuelyaman does not explicitly teach that the second facing layer is composed of a skin adherent hydrophobic silicone gel. However Abuelyaman teaches that the second absorbent layer/second facing layer functions as a barrier between the first absorbent layer comprised of the instant gel material and is less absorbent than said gel material. Since Abuelyaman teaches that the gel material comprises a hydrophobic monomer, it would be obvious to one of ordinary skill in the art to modify the second absorbent layer/second facing layer so as to be comprised of a skin adherent hydrophobic gel. Silicone gel is an example of a hydrophobic gel that would accomplish the identical function of acting as a barrier to other hydrophobic gel monomers taught by Abuelyaman, therefore it would be obvious to one of ordinary skill in the art to modify the article of Abuelyaman such that the second facing layer comprises a skin adherent hydrophobic gel with a reasonable expectation of success to preserve the function of the second facing layer as a barrier between the wound and said first absorbent layer.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abuelyaman in view of Bogart (U.S. Patent No. 5,512,041).

With respect to **claim 20**: Abuelyaman does not teach that the peripheral edges of the absorbent core 12 have a bevel extending downwardly and inwardly towards a central axis thereof from the distal surface to the proximal surface thereof. Bogart teaches a wound dressing having an absorbent core with a bevel extending downwardly and inwardly towards a central



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axis thereof from the distal surface to the proximal surface thereof. Since the articles of Abuelyaman and Bogart seek to solve a similar problem in the art (i.e. provide a wound dressing for absorbing wound exudates, it would be obvious to one of ordinary skill in the art to modify the article of Abuelyaman such that the absorbent core has a bevel as taught by Bogart with a reasonable expectation of success.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abuelyaman ('143) in view of de Jong et al (U.S. Patent Application Publication No. 2003/0120229).

With respect to **claim 23**: Abuelyaman teaches a wound dressing 10 having opposed bodyside and backside surfaces, the bodyside surface being generally planar as can be seen in Fig. 1 and defines the outermost surface on a proximal side of the dressing intended to be directly placed adjacent a wound surface, comprising: an absorbent core 12 defining opposed proximal and distal surfaces 14, 16, respectively; a liquid impervious, vapor permeable backing layer 18 defining opposed proximal and distal surfaces, the proximal surface of the backing layer 18 extending over the distal surface of the absorbent core 12, and defining a border portion 22 extending beyond and surrounding peripheral edges of the absorbent core 12, the distal surface of the backing layer 18 defining the backside surface of the wound dressing 10; and a continuous skin adherent facing layer 26 directly secured to both the proximal surface of the absorbent core 14 and the proximal surface of the border portion 22 of the backing layer 18, the facing layer defining a pattern of through extending apertures only along an apertured portion thereof adjacent to the distal surface 16 of the absorbent core and bounded by the peripheral edges of the absorbent core 18, the portion of the facing layer 26 corresponding to the border portion 22 of the backing layer having a generally smooth surface, the facing layer 26 defining

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the entirety of the bodyside of the wound dressing 10. (Fig. 1, Col. 19, lines 16-28, 53-67, Col. 20, lines 1-9) The continuous facing layer is formed from a pressure-sensitive adhesive layer comprising... as taught by reference to Ulrich RE 24,906)

Abuelyaman does not teach that a polymeric foam based core 12. However the use of such polymeric foams as absorbent core materials is well known in the art of wound dressings as supported by de Jong (¶0007), therefore it would be obvious to one of ordinary skill in the art to modify the wound dressing of Abuelyaman such that the core 12 is comprised of polymeric foam based absorbent core with a reasonable expectation of success to ensure that the wound dressing aptly provides the function of absorbing wound exudates.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on August 31, 2007 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand  
Examiner  
Art Unit 3761

October 19, 2007

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

